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Subject: PPDC Reg

Dear Workgroup members,

The PPDC Registration Review Workgroup will convene by teleconference on Tuesday, January 6 from 2:30 to 4:30 p.m. EST.

Please call [phone number deleted]

Then enter the access code: [deleted]

and remember the asterisk (*) before and after the access code number!

Proposed Agenda:

- 1) Status of the PPDC Registration Review Workgroup in developing procedural regulations
- 2) Schedule for meetings and teleconferences
- 3) Identify issues
- 4) Agenda for next meeting

Below are 2 items to help you with agenda item 3

Item A -- List of Issues

Item B -- Process for Starting Registration Review

ITEM A -- List of Issues

Criteria for scheduling

Criteria for Registration Review case formation

Process for announcing schedules

Criteria and process for changing the registration review schedule

Define “registration review” – determination whether a pesticide meets standard of FIFRA 3(c)(5)

Define possible outcomes of a registration review– meets FIFRA section 3(c)(5); doesn’t meet FIFRA section 3(c)(5); defer decision pending completion of required studies?

Process for assessing end-use products

Process for assessing inert ingredients

What should the procedural regulations say about the scheduling process?

What should the procedural regulations say about the registration review process?

Should the procedural regulations include registration review decision criteria?

Should the procedural regulations address timeframes for completing a registration review (e.g., when a FIFRA 3(c)(5) decision can’t be made until data gaps are filled)?

What activity initiates a pesticide’s Registration Review?

Should EPA require registrants to submit a registration review application?

Consequences for failure to submit a required registration review application.

Process for stakeholder involvement – prescriptive or general statement of principle (i.e., degree of public involvement commensurate with the complexity of issues in a pesticide’s registration review?)

Transaction costs for registrants and other stakeholders.

Factors to consider when asking “what has changed since the last review?”

Incentives for registrants to submit studies and data “voluntarily” (i.e., before a DCI is issued)

Impacts on small businesses

ITEM B -- Process for starting registration review

1. Develop master schedule
2. Each year announce schedule for the following year
3. Registration review application required? [discussion issue]

- a. YES: Set due date 3 months before start of the pesticide's registration review.
 - b. NO:
4. Solicit comments from stakeholders? [discussion issue]
- a. YES: Comment period begins 3 months before start of the pesticide's registration review.
 - b. NO: Stakeholders would comment on draft registration review decision.
5. Did registrant submit registration review application if required in step 3?
- a. YES: Did the application include information that EPA required?
 - i. YES. Go to step 6.
 - ii. NO. Go to step 5b.
 - b. NO: Initiate cancellation under FIFRA section 6(b)
6. Assemble information that will be reviewed, including registrant's application (if required in step 3) and stakeholder comments (if requested in step 4).
7. Conduct review. Go to flow chart drafted by PPDC Registration Review workgroup.